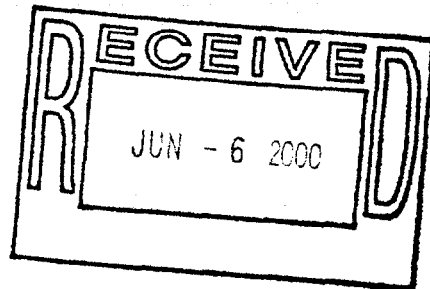




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May 31, 2000

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Zypan supports protein digestion and absorption.
- (2) The betaine portion of this essential compound comes from choline and works to synthesize the amino acid methionine from homocysteine. Hydrochloride (HCL) is an acid found in gastric juice that controls many digestive and metabolic functions – of which the digestion of proteins – is the most important. The bovine pancreas Cytosol™ extract in Zypan provides materials produced by the pancreas, including acids, and to support corresponding human tissue. Pancreatin is a proteolytic enzyme taken from animal pancreas secretions that can help support a healthy pancreas in humans. Pepsin, also a proteolytic enzyme is secreted in the stomach to hydrolyze protein for absorption. Bovine and ovine spleen tissue proteins provide additional support at the cellular level.
- (3) Zypan maintains cellular health.
- (4) Essential fatty acids are needed by every living cell in the body to produce new cells and to rebuild damaged cells.
- (5) Zypan is a multiple enzyme product containing proteolytic enzymes in combination with pancreatin, ammonium chloride, and betaine hydrochloride to support the digestion and absorption of proteins.
- (6) Zypan contains betaine hydrochloride -an acidifying compound that serves as a building block to the hydrochloric acid needed in the stomach for digestion. Betaine Hydrochloride joins forces with proteolytic enzymes to boost protein digestion and absorption.

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**Standard  
Process®**

- (7) Pancreas Cytosol™ extract plus spleen glandulars offer tissue support for the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of betaine hydrochloride, pancreas Cytosol™ extract, pancreatin (3X), fatty acid, pepsin (1:10,000), ammonium chloride, bovine spleen, and ovine spleen. Other ingredients include cellulose, lactose, and calcium stearate. The name of the product is Zypan®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.